

REMARKS

Claims 1-46 constitute the pending claims in the present application. Among them, Claims 20-23 are allowed, and Claims 2-8, 10, 12, 13, 24, 26-30, 32-34, and 36 are objected to.

Applicants have amended Claims 1, 15-17, 19-21, 27, 31, 32, and 43 to correct obvious typographic and/or grammatical errors and to simplify claim language. Applicants submit that these amendments neither introduce new matter nor narrow the scope of the amended claims.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Claim Objections

The Examiner objects to Claims 19 and 43 because of informalities.

Applicants have adopted the Examiner's suggestions to amend Claims 19 and 43 to obviate these objections. Applicants submit that these amendments do not introduce new matter, and do not narrow the scope of the claims. Reconsideration and withdrawal of the objections are respectfully requested.

Rejection of Claims 1, 9, 11, 14, 15, 25, 31, 35, 37, 40, 41, and 44-46 Under 35 U.S.C. § 102(e) as being anticipated by U.S. Pat. No. 5,848,991 (Gross et al., Ref. A)

Specifically, the Examiner states that the preamble term "for collecting a sample of a biological fluid" was "not given any patentable weight and was not considered a limitation, since the body of the claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations."

The Office Action also deems reservoir **10** in Gross as the recited collection chamber, "because there is no structural difference between the claimed collection chamber...and the reservoir of Gross."

Applicants respectfully disagree, because, as amended, the phrase which modifies "collection chamber" i.e., the phrase "suitable for collecting a sample of a biological fluid" does not merely recite an intended use, but indeed imparts a structural limitation on the collection chamber, which structural limitation is not taught or suggested in Gross.

The entirety of the subject specification clearly indicates that the collection chamber must be constructed in such a way that it can collect or draw fluid from outside the chamber into the chamber. There are key structural differences between such a collection chamber and the reservoir of Gross, though both may be in fluid communication with the base ends of microneedles. To clarify the subject matter claimed, Applicants have amended Claim 1 to explicitly recite that the “collection chamber” is “suitable for collecting a sample of a biological fluid.” Applicants submit that this amendment does not narrow the scope of the claim.

Gross does not teach or suggest that the reservoir in the various disclosed embodiments can be used as a collection chamber. Indeed, many (if not all) of them are *structurally different*, and thus cannot be used as the recited collection chamber. For example, in its preferred embodiment as shown in Figure 3, Gross teaches that reservoir 10 can be compressed by generating a gas in gas chamber 12 (see col. 7-8 and Figure 3 of Gross). Gross neither teaches nor suggests how such a reservoir can be operated in reverse to expand the reservoir, because this would require the generation of a negative pressure in gas chamber 12. In other words, reservoir 10 in Figure 3 is structurally different from, and thus cannot function as, the recited collection chamber.

Similarly, in the embodiments described in Figures 4 and 5 of Gross, the spring or flexible membrane is in a relaxed position when the reservoir is empty. The spring or membrane is only forced into its stressed position when a drug fluid is filled into the reservoir. Gross neither teaches nor suggests how this type of reservoir can be used as a collection chamber. Neither the spring nor the membrane can stay at a stressed position without a counter-balancing force, and . Gross does not teach or suggest such a modification.

The same argument applies equally to the embodiment described in Figure 6 of Gross, which does not teach or suggest how reservoir 10, with its taut structure, can function as a recited collection chamber.

Regarding the rejection of Claims 15 and 31, Applicants have amended Claim 15 to clarify the subject matter claimed. Support can be found throughout the specification, see, for example, page 9, last paragraph.

Applicants respectfully submit that the Examiner has misinterpreted the disclosure of Gross and the instant specification, because the sensor in the claimed invention is different from those in Gross.

The claimed sensor senses analytes in a biological fluid, such as biological fluid drawn from the one or more microneedles. Thus the sensor is in “fluid communication with the microneedles.” In contrast, the sensor of Gross measures something *external* to the drug stored inside the reservoir (for example, Gross measures body temperature, pulse rate, blood pressure, see col. 8, lines 30-36 in Gross). Despite the cursory reference to blood pH or blood glucose level in Gross, nowhere in Gross it is disclosed that these parameters are measured using sensors “in fluid communication” with any microneedle. In fact, that need not be and indeed cannot be, since the microneedles in Gross are for injecting drugs into patients, not for withdrawing body fluid (such as blood) from that patient. In addition, the sensor controls the microneedle indirectly, through microprocessor 20 (see col. 8, first paragraph).

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP 2131. Gross fails to teach or suggest at least one structural element of each of the subject claims, and thus Gross cannot anticipate the claimed invention. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims 16-19 Under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 5,848,991 (Gross et al., Ref. A) in view of U.S. Pat. No. 5,722,397 (Eppstein et al., Ref. B)

The Examiner argues that Gross teaches the use of a blood glucose sensor, but fails to teach the particulars of the blood glucose sensor, while Eppstein allegedly cures the defect.

In view of the defect of Gross discussed above, and because Eppstein does not correct this defect, Applicants submit that the combined teaching still fails to teach or suggest all the limitations of the claimed invention, even assuming without agreeing, for the sake of argument, that there is motivation to combine Gross and Eppstein.

Thus, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

Rejection of Claims 38, 39, 42, and 43 Under 35 U.S.C. 103(a) as being obvious over U.S. Pat. No. 5,848,991 (Gross '991) in view of U.S. Pat. No. 5,807,375 (Gross '375)

The Examiner argues that Gross '991 teaches a delivery needle, but fails to teach the material of the needle, while Gross '375 allegedly cures the defect.

In view of the defect of Gross '991 discussed above, and because Gross '375 does not correct this defect, Applicants submit that the combined teaching still fails to teach or suggest all the limitations of the claimed invention, even assuming without agreeing, for the sake of argument, that there is motivation to combine Gross '991 and Gross '375.

Thus reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that all pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**, under Order No. **BVTP-P01-539**.

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